Congress of the United States
House of Representatives
Washington, DC 20515

May 26, 2004

The Honorable Joshua Bolten
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Bolten:

In December several of us wrote expressing a number of concerns about the proposed Peer Review Guidelines. We indicated that the proposal was unjustified, overly broad, burdensome, and did not appropriately guard against appointment of reviewers with conflicts of interest. We also expressed our concern that the proposal provided the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) with excessive authority over the production and dissemination of government information. The revised proposal does not address these concerns.

In our view, the revised guidelines do not strengthen peer review policies across the federal government. Instead they invite politicization of science at federal agencies by placing control over the development and dissemination of federal information in a policy office -- OIRA. The proposal is not tailored to ensure that the more rigid peer review requirements imposed by this Bulletin are restricted to "the more important information disseminated by the federal government." These procedures will obstruct the dissemination of agency information, particularly in matters related to public health and safety and the environment.

The proposal continues to grant OIRA excessive authority over the development and dissemination of agency work products. The proposal remains unjustified, overly broad, and burdensome. Despite the addition of language indicating that agencies may be permitted some flexibility in applying the criteria established in the Bulletin, we still believe the prescribed structure is too rigid and inflexible to permit agencies to tailor peer reviews to individual information products they produce. The proposal still does not safeguard the established review process from manipulation by special interests.

We do note that the adoption of some of our recommendations and some of the recommendations of the scientific community has resulted in an improved draft. In particular, we support the exemption for time-sensitive medical, health and safety information. The elimination of the restriction on the ability of federally-funded scientists to serve as peer reviewers of agency information also represents an improvement.

However, these modifications do not address our major concerns with the proposal. We continue to believe the proposal is unjustified and burdensome. The proposal should be withdrawn or substantially revised to maintain agency authority over the development and review of information.

Our comments on specific problems with the revised guidelines follow.

The Proposal Remains Unjustified

The proposal states: "A large variety of authorities have argued that peer review practices at federal agencies need to be strengthened." This statement is not supported by any recent assessment of peer review practices at federal agencies. If OIRA or the Office of Science and Technology Policy (OSTP) undertook such a review in the development of this Bulletin, the summary document and its findings have not been cited or discussed in the justification of the Bulletin.

In addition, none of the studies cited in footnotes 4, 5, 6 and 7 of the Bulletin provide justification for any such broad-based statement. These references do not provide the background to support the need for this Bulletin or for the establishment of agency peer review policies by OIRA. Six of the ten studies cited are five or more years old.[1] The four recent studies neither survey nor assess federal agency peer review processes.[2] The 2002 GAO study on the Endangered Species Program does not address peer review policies used in that program at all. The 2001 GAO study of EPA's Science Advisory Board (SAB) addressed issues related to the selection of reviewers serving on SAB panels. EPA has since altered its policies and now utilizes an appointment process similar to that of the National Academy of Sciences.

The continued citation of 2002 report on a pilot study by EPA's Office of the Inspector General is troubling. This report is an obvious example of something that would never have withstood peer review as a representative study. The Report states: "The rules included in the pilot study were not a representative statistical sample of EPA rules, and we did not identify all of the critical science inputs for every rule."[3] This study provides no justification for altering EPA's peer review procedures.

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[1] U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D. C., 1999; Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision-Making, Carnegie Commission, New York, 1993; National Academy of Sciences, Peer Review in the Department of Energy—Office of Science and Technology, Interim Report, National Academy Press, Washington, D.C., 1997; National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D. C., 1998; Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991; National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D. C., 1994.

[2] National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practices, National Academy Press, Washington, D.C., 2000; U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, Washington, D.C., 2001; U.S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, DC, 2002, U.S. General Accounting Office, Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized, GAO-02-581, Washington, D.C., 2002.

[3] U.S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, DC, 2002. (p. 10).

The 1998 and 1999 studies of DOE's Office of Science and Technology (OST) done by the National Academy of Sciences (NAS) found that OST had made "significant improvements in its peer review process since the program began in October 1996."[4] The NAS study of EPA's Science done in 2000 contains recommendations that management of peer review be separated from the management of a document's production.[5] No recommendation suggests that management of the peer review process should be separated from the agency. The report cites a Science Advisory Board study attributing improvements in EPA's peer review policy to greater involvement of EPA's Office of Research and Development in the peer review process.[6]

Neither of the Carnegie Commission reports cited provide justification for an OIRA-managed, uniform federal peer review policy. The report on math and science education has little to say about peer review even in the Department of Education and the National Science Foundation, the two federal organizations addressed in the report.[7]

The Carnegie Commission report on Improving Regulatory Decision-making contains minimal reference to peer review. It does not contain any recommendation for oversight of agency peer review policies by OIRA. In fact, the report contains a chapter devoted to regulatory review procedures in the Executive

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[4] National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D. C., 1998. "The committee finds that OST has made significant improvements in its peer review process since the program began in October 1996. Throughout the committee's study, OST has continued to change its peer review procedures in an effort to improve the program's effectiveness. In particular, OST has revised its review criteria to focus on technical issues, has developed a more systematic approach for selecting projects to be reviewed, and has modified its list of required documentation for the peer reviews. OST also has made a number of policy changes since this committee issued its interim report in October 1997 (see Table 1 and the main body of this report for more details on these policy changes). Although in many cases it is too early to judge the actual results of these changes, the committee is encouraged that OST senior management appears to be committed to this improvement process." (p.6)

[5] National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practices, National Academy Press, Washington, D.C., 2000. "Change the agency's peer-review policy to more strictly separate the management of the development of a work product from the management of the peer review of that work product, thereby ensuring greater independence of peer reviews from the control of program managers, or the potential appearance of control by program managers, throughout the agency." (p. 145)

[6] ibid. The SAB "praised the Agency's diligence and high-level management commitment to peer review." (p.120). Significantly, the SAB also concluded that "the key to success in implementing the peer review process has been the involvement of ORD [Office of Research and Development] in the oversight role, and that 'ORD scientists have an understanding of the importance of peer review in developing good scientific and technical products'" (p.123).

[7] Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991. The report does not provide an assessment of federal peer review policies. The report refers to the peer review policies of NSF favorably. The report states: "NSF accesses the best research capabilities in the nation, including cognitive science and learning research that should inform strategies for educational improvement. It is experienced in running competitive programs to support the best ideas arising outside the government and has an excellent reputation for integrity, technical sophistication, and the use of peer judgment in program selection."

Office of the President – some of which is critical of past Administrations that utilized regulatory review to stifle legitimate agency actions.[8]

Your proposal asserts that more widespread use of peer review will result in fewer legal challenges to federal regulations. This is an assertion with no basis in experience. The EPA rule establishing a National Air Quality Standard for fine particulate matter[9] included an extensive amount of information that was peer reviewed. The criteria documents synthesized information from hundreds of peer reviewed published studies.[10] The criteria documents themselves were subject to peer review by the Clean Air Scientific Advisory Committee.[11] The epidemiological studies referenced in the rule were peer reviewed, audited, and re-analyzed by the Health Effects Institute[12]. The rule was still challenged. Effected parties bring legal challenges because they wish to block or initiate regulatory activity to achieve a desired policy outcome. Peer review will not resolve divergent policy preferences. It is unreasonable to expect science to resolve policy differences.

In summary, OIRA cannot provide any current analysis that identifies any systemic problem with peer review processes at federal agencies. The revised Bulletin provides no estimate of the potential scope and cost of the proposed changes. OIRA should hold its initiatives to the same standard it applies to federal agencies. The government should not adopt costly new procedures without estimating the costs and without clearly demonstrating that such policies are needed to address an identified problem.

Unbalanced Approach to Federal Information Review

The revised proposal has reduced the scope of information subject to the review procedures mandated by the Bulletin. This has been accomplished through the use of exemptions, leaving unbalanced application of mandated review of federal information.

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[8]Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision-Making, Carnegie Commission, New York, 1993. Chapter 3: The Executive Office of the President: Policy Formulation and Regulatory Review.

[9]National Ambient Air Quality Standards for Particulate Matter; Final Rule. Federal Register July 18, 1997, Vol. 62, No. 138: 38651-38701.

[10] Air Quality Criteria for Particulate Matter (Criteria Document), EPA/600/P-95-001aF through EPA/600/P-95-001cF, April 1996.

[11] U.S. EPA, Clean Air Science Advisory Committee, Closure by the CASAC on the Draft Air Quality Criteria for Particulate Matter, EPA-SAB-CASAC-LTR-96-005, 1996, U.S. EPA Clean Air Science Advisory Committee, Closure by the Clean Air Scientific Advisory Committee on the Staff Paper for Particulate Matter, EPA-SAB-CASAC-LTR-96-08, 1996; U.S. EPA Clean Air Science Advisory Committee, CASAC Closure on the Air Quality Criteria for Ozone and Related Photochemical Oxidants, EPA-SAB-CASAC-LTR-96-001; U.S. EPA Clean Air Science Advisory Committee, CASAC Closure on the Primary Standard Portion of the Staff Paper for Ozone, EPA-SAB-CASAC-LTR-96-002.

[12] Health Effects Institute, Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Final version, July 2000.

Information related to public health, safety and the environment continues to be subject to the prescriptive peer review approach mandated by the Bulletin. Information related to economic, tax, trade, and national security policy is exempt from this policy, despite its significant impact on government and private expenditures and its importance to policy-making. Information supporting the entry of products into the marketplace is exempt. Information supporting the removal of products from the marketplace that endanger health and safety is covered unless emergencies powers are invoked. This pattern of exemptions does not conform to the stated purpose of the Bulletin to promote more uniform review procedures for information of similar import to public policy.

The broad nature of exemptions numbered 1, 6, and 7 would permit different levels of review and public scrutiny to be applied to information generated by different federal agencies on the same topic. For example, it is clear that any information produced by EPA will be subject to this Bulletin, while much, if not all, information produced by the Department of Defense (DOD) will be exempted because it is "*related* to national security." (emphasis added)

Currently, DOD and EPA hold differing views of the human health risk of perchlorate in drinking water. DOD and EPA each have produced information to support their view. There is no assurance under this policy that information produced by DOD will be subject to the same review and public scrutiny as the information produced by EPA. There is also no assurance EPA's information already produced under a more transparent and public process will be given deference in setting policies related to standards for perchlorate in drinking water or to set clean up standards for contaminated areas.

The scientific community undoubtedly welcomes the exemption for information produced by government-funded scientists using extramural or intramural funds from federal agencies. This is a useful exemption that will continue to permit scientists to disseminate their findings to their colleagues and to the public.

However, we note this exemption only holds "if those information products are not represented as the views of a Department or agency." If a journal article were to be cited as part of an agency document synthesizing information from multiple journal articles or combining agency-generated information with work produced through extra-mural funding, it may be subject to the review procedures mandated by the Bulletin. The articles on the health effects of particulate matter published by researchers at Harvard University and by researchers at the American Cancer Society[13] provide such an example. An author producing information for public distribution has no control over the ultimate use of this information by federal agencies or other organizations. OIRA may insist, even over the objection of the agency, that a peer reviewed journal article should also be reviewed under the procedures required by the Bulletin if the work is utilized to develop and implement policy.

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[13] Dockery, D.W., C. A. Pope, III, X. Xu, J.D. Spengler, J. H. Ware, M. E. Fay, B. G. Ferris, Jr., and F.E. Speizer, An Association Between Air Pollution and Mortality in Six U.S. Cities, New England Journal of Medicine, Vol. 329: 1753-1759 (December 9) 1993; Pope, III, C. A., M. J. Thun, M. M. Namboodiri, D. W. Dockery, J. S. Evans, F. E. Speizer, and C. W. Heath, Jr., Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U. S. Adults, American Journal of Respiratory and Critical Care Medicine, Vol. 151: 669-674, 1995.

The scope of information subject to the Bulletin for covered agencies has been reduced very little. Definitions of "influential scientific information," "scientific assessment," "scientific information", and "highly influential scientific assessment" continue to encompass a substantial amount of information for covered agencies.

Influential scientific information "means scientific information the dissemination of which the agency reasonably can determine that dissemination of which will have or does have a clear and substantial impact on important public policies or private sector decisions." This definition still contains no meaningful boundaries. The determination of importance is subjective and it could be argued that much of the information generated by agencies, particularly regulatory agencies, is intended to influence public policies and private sector decisions.

The Bulletin's Section III review process will apply to all information falling into the category of highly significant information -- any "scientific assessment" "the agency *or the Administrator* determines ...*could* have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than $500 million per year" or that the agency *or the Administrator* determine involves precedent setting, novel, and complex approaches, or significant interagency interest." (emphasis added)

Increasing the numerical value of the threshold contained in the definition may be meaningless in the context of an individual agency information product. Methods to evaluate the potential economic impacts of a rulemaking are controversial and not well-developed. It would be difficult, if not impossible to evaluate the potential economic impact of an information product. Essentially, any agency information product that the Administrator of OIRA determines should be reviewed in accordance with Section III of this bulletin will be subject to this prescribed review.

The definition of highly influential information affords the Administrator of OIRA total control. Any information presented by a federal agency will be subject to the Bulletin's mandated review as long as the Administrator of OIRA determines that an assessment could be relevant to the Administration's agenda.

Although Section II of the Bulletin states: "agencies are granted ...*appropriate discretion to weigh the benefits and costs* of using a particular peer review mechanism for a particular agency product.", it appears to us that agency discretion regarding the form and the level of review will in practice be limited. Under Section II agencies are directed to consider "at least" seven issues in selecting a peer review mechanism for an information product -- issues "relevant to any peer review under this Bulletin."

In practice, to avoid preparing and defending justifications of review alternatives that do not include all seven components (including preparation of a cost benefit analysis) and to avoid accusations of inadequate peer review, agencies likely will perform peer reviews that conform to all the procedures outlined in the Bulletin.

The Bulletin provides three options for peer reviewing information falling into the highly influential category. One is prescribed in the Bulletin, the second is to commission the National Academy of Sciences (NAS) to do the peer review, and the third is for the agency to negotiate a peer review process with OIRA.

The listing of three options for meeting the requirements for the peer review of highly significant information grants flexibility to OIRA, not to the agencies. As stated in the preamble to the Bulletin: "This Bulletin imposes *minimum* (emphasis added) requirements for the peer review of highly influential scientific assessments."

OIRA's authority over the review process is extensive (Sections III 1; IV(iii); IX). The oversight role enables OIRA to: challenge an agency's designation of a peer review as adequate; challenge an agency's designation of information as influential or highly influential; require additional reviews or special review procedures; determine an agency's response to peer reviewer's comments requires additional research to resolve uncertainties prior to information being disseminated.

There is an illusion of agency discretion here, but it is very limited. When this proposal is viewed in its entirety, considering the mandatory Peer Review Planning procedures of Section V and OIRA's oversight role, agencies will have limited discretion to deviate from a peer review structure that includes all components prescribed in the Bulletin.

We are pleased that agencies will continue to have the option of commissioning work from the NAS. In fact, the Bulletin may create an incentive for agencies to turn to the NAS more frequently since NAS work is assumed to be in compliance with the Bulletin. However, exercising this option will raise the cost of peer review.

Burdensome Approach Affording Multiple Opportunities for Delay

The Bulletin creates considerable new burdens on agencies producing information in support of policies in the areas of public health, safety and the environment. Under this policy, agencies must produce justifications, including some form of cost benefit analysis, to support their determinations of a previous peer review's adequacy and their designations of information as influential or highly influential. Agencies must prepare Peer Review Agendas and conduct ongoing public comment processes on the information they contain. They must also find the financial resources to support the reviews required under the Bulletin. Finally, the Bulletin creates opportunities for controversial information produced by agencies to be trapped in an endless cycle of review.

An "adequate" peer review is required for all "influential" information an agency intends to disseminate. An agency wishing to disseminate information that has already been peer reviewed must make a determination that the peer review was adequate and justify this determination in terms of benefits and costs. The Bulletin states:

> "An agency may deem a prior peer review adequate if it determines that the peer review was sufficiently rigorous in light of the novelty and complexity of the science to be reviewed *and* the benefit cost implications." (emphasis added)

A benefit cost analysis may also be necessary to apply a peer review procedure that does not conform to all procedures mandated by the Bulletin. Only peer reviews done by the National Academy of Sciences are generally presumed adequate. This requirement will force agencies to either perform a cost benefit analysis to justify a different peer review procedure, to adopt the prescription for review of the Bulletin, or to fund a peer review by the NAS.

The requirement for agencies to establish a Peer Review Agenda (Section V) is particularly onerous and unnecessary. Numerous publicly available documents provide information about current and planned agency activities. Statutes, mission statements, strategic planning documents, Congressional hearing records and annual agency budget justifications all provide information to the public about the range of agency activities including information collection, research and development, and rulemaking. Scientific journals, magazines, newspapers and other media outlets track current scientific and policy issues. Rulemakings now take in excess of five years to complete and comprise numerous steps and provide numerous opportunities for interaction between agencies and interested parties.

Some agencies (e.g. EPA) now provide a listing for planned or ongoing peer reviews.[14] A database such as EPA's provides the public with extensive information about completed and planned projects. However, the requirement in Section V of the Bulletin for agencies to include information defining all aspects of the peer review process to be used for each scientific information product, to update the list "*at least* every six months" (emphasis added), and to accept and consider public comments on the listed peer review plans would consume considerable agency resources and severely limit agency flexibility.

Agencies should retain the flexibility to add, delete, and change listed items as situations arise without having to respond to public comment on all changes. It is not always possible for agencies to anticipate all peer review activities over a given period of time. In some instances, peer reviews or peer review plans may need to be altered in response to court orders or unforeseen circumstances. The requirement for all peer review information to be posted and available for public comment suggests that peer reviews may not proceed unless this requirement is fulfilled, resulting in delay in the completion of agency work products.

This requirement appears to be designed to facilitate OIRA's oversight of this Bulletin rather than to improve review of agency work products. The public comment requirement invites anyone interested in delaying progress of agency work to issue challenges to agencies' designations of information as influential or highly influential and to issue challenges to planned agency peer review procedures.

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[14] EPA's Science Inventory Database contains information on science products, project descriptions, and planned peer reviews of agency studies. The Database is accessible through EPA's website at www.epa.gov/si.

Agencies should be permitted to conduct their day-to-day work without having to respond to an ongoing notice and comment procedure.

Once a peer review has finally been completed, there is no guarantee in the Bulletin that compliance with the Bulletin once will ensure distribution of agency information. An information product could become trapped in an endless cycle of review and refinement.

One way this could happen would be for the "use" of information to shift. A peer review of an influential scientific assessment under the criteria defined by Section II of the Bulletin does not preclude an additional peer review of the same scientific assessment if at a later time OIRA or the agency determines the scientific assessment has become highly influential. The Bulletin states clearly in the description of the requirements for Section III: "Typically, the data and models used in scientific assessments have already been subject to some form of peer review (e.g. refereed journal peer review *or peer review under Section II of this Bulletin*)." (emphasis added) The level of review for any information is dependent upon OIRA's view of its importance. Therefore if OIRA's view changes more review is required.

Another path to endless review is through peer reviewers' recommendations for further research. The discussion on the development of an appropriate charge to review teams in the Scope of Review for Section II states:

> "...peer reviewers might be asked to consider value-of-information analyses that identify whether more research is likely to decrease key uncertainties."

There are several problems with including this in the charge to the reviewers. First, since the inevitable answer to this question is yes, it ensures that all panels will include a list of proposed research aimed at resolving uncertainties in the reviewers' report. The agency must respond to the reviewers' report including a statement of the actions they intend to take to address reviewer comments. The inclusion of this direction in the charge to the reviewers is an invitation to supply the documentation of need for additional study and to stall information dissemination until that work is completed. It deflects the focus of the review from one to assess the overall quality of the agency's work product to one that provides a blueprint for further research. Under these conditions, even a document that has been adequately reviewed may not be disseminated after the review is completed.

OIRA could determine that the agency has not responded appropriately to the need for additional research identified by the reviewers in their report. If new research is undertaken or research in progress at the time of the review is utilized to produce a revised document OIRA could require the agency to review the revised document. These guidelines design a system that favors review and revision of information, not its dissemination.

The bulletin claims that the President's Commission on Risk Assessment and Risk Management recommends these analyses as tools for peer reviews. This is untrue. The Commission's report refers to value-of-information techniques being used by *decision-makers* to balance "the value of obtaining

additional information against the need for a decision."[15] In the same paragraph, the report states: "Every effort should be made to avoid "paralysis by analysis" where the need for additional information is used as an excuse to avoid or post-pone decision-making."[16] Similarly, value-of-information techniques are suggested for use by *risk managers* to resolve the dilemma between making a decision in the face of uncertainty and opting to gather additional information to reduce uncertainty before making a decision.[17]

Conflict of Interest, Independence and Balance

We support the revision to the proposal clarifying that receipt of agency funding, particularly through extra-mural grant programs, does not preclude participation of non-federal experts from serving as peer reviewers. However, we remain concerned that safeguards to ensure the integrity of the process for selection of reviewers have not been included in the Bulletin.

The Bulletin provides an agency with the option to utilize an outside entity to perform the peer review. Although the requirements of the Bulletin are to apply to these "entities" it is unclear whether these entities will be subject to the full range of guidelines and statutes (e.g. Federal Advisory Committee Act (FACA), Privacy Act, etc.) as the agency. Also, the Bulletin fails to consider or preclude the agency using an "entity" that may itself have a conflict of interest with regard to the document under review. For example, the "entity" may have other contracts with regulated entities to develop or review documents that are incorporated in or related to the government document under review.

The language of the Bulletin in Sections II4 and III2b implies that participation by persons with a conflict of interest is to be expected. "To properly handle participation by scientists with a conflict of interest..." The Bulletin then provides options to ensure that minimal standards are met to gather information used to document potential conflicts.

We realize there is a need for flexibility in choosing members to serve on review panels, and participation by an individual with a conflict of interest may be appropriate in some circumstances. However, effort should be made to minimize participation by persons with conflicts of interest. The guidelines provide weak direction in this area. There is no requirement that agencies disclose publicly whether any panel members with a conflict were selected.

The guidelines direct agencies to ensure that all federal employees comply with federal ethics requirements and expand these requirements for reviewers who are not federal employees. This policy provides minimal standards that are recognized as insufficient to ensure public confidence in the process.[18]

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[15] Presidential Commission on Risk Assessment and Risk Management. Risk Commission Report. 1997. Vol. 1: 39.
[16] ibid
[17] President's Commission on Risk Assessment and Risk Management. Risk Commission Report. 1998. Vol. 2: 91.
[18] U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, June 2001 GAO-01-536; The National Academies, Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, 2003.

Information provided in compliance with federal ethics statutes, on Office of Government Ethics (OGE) Form 450, is limited in its focus. The GAO report on the procedures to ensure balance and independence in appointments to EPA's Science Advisory Board noted: "While the information it [OGE Form 450] elicits covering the prior year is pertinent to assessing financial conflicts of interest, it does not identify other information relevant to assessing impartiality and balancing peer review panels."[19] EPA has since made changes to its policies to incorporate the GAO recommendations made in this report. It is not sufficient to simply require information to be collected on conflicts of interest. There must be a requirement to evaluate and act upon this information to ensure the formation of a panel that will inspire public confidence in the process. The current language of the Bulletin does not accomplish this important goal.

NAS policy on consideration of conflicts of interest goes beyond the minimal requirements of this Bulletin. NAS policy recognizes that public confidence in their products can be undermined unless the process is "fairly balanced in terms of knowledge, experience, and perspectives utilized to produce it and free of any significant conflict of interest." The NAS policy also states: "Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed."[20]

The NAS standards are stricter than the federal standards referred to in the Bulletin. The guidelines direct agencies to "*consider* the conflict of interest policy used by NAS" (emphasis added), but they do not have to adopt them.

The statement in Section II 4(iii): "For scientific assessments *relevant to specific regulations*, a reviewer's financial ties to both regulated entities (e.g. businesses) and the agency should be examined." (emphasis added). Since these reviews are intended to be pre-regulatory, the information being reviewed may not be tied to any specific regulation. Again, the agency is directed only to examine the information not to act upon it.

The entire discussion pertaining to selecting an independent panel focuses on independence from the agency that has produced the information with little discussion about the importance of considering a panel member's independence from regulated entities. Even in the reference to the policies utilized by the NAS in selecting panel members, Section III c(iii) states the policies to be considered are the practices of NAS "concerning ties of a potential committee member *to the sponsoring agency.*" (emphasis added). Any panel selected should be operating and offering advice that is independent of all entities that were involved directly with the development of the product under review and with an interest in the policy implications of the product.

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[19] U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, June 2001 GAO-01-536. (p.12).

[20] The National Academies, Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, 2003. (p. 4).

The Bulletin's language on Expertise and Balance included in Section III 2a pertains only to the consideration of balance of scientific perspective. This narrower definition of balance may be adequate for the review of strictly scientific and technical information. However, by the definitions of this Bulletin the documents to be reviewed are not strictly scientific and technical. They are policy-relevant documents. Consideration must be given to the potential policy biases that all members of these panels are going to bring to the table.

As Dr. Jasanoff pointed out in her comments on the initial proposal:

> "In general, peers for conducting peer review will be hardest to identify and are most likely to produce inconsistent or unhelpful reviews when the science in question has the following properties:
> - It is emergent. That is, neither the knowledge base not the methods for producing it are firmly established in advance.
> - It is characterized by high uncertainty (with respect to data) and low consensus (with respect to methods).
> - It is the product of interdisciplinary methods.
> - It is politically sensitive.
>
> All these characteristics are frequently present in regulatory science (particularly so in the case of significant regulatory information), making the identification of independent, objective peers both difficult and controversial."

The Bulletin fails to address or even to acknowledge the need to consider the overall balance of the committee with respect to a balance in points of view. This omission will result in a lack of public confidence in the panel selection process and in the panels that emerge from it.

Information Access and Data Quality

The information access provision (Section III 3) does not include safeguards to ensure the integrity of the information product under review or the underlying data, models, and other background information that were considered in the development of the overall information product. This provision also suggests an inappropriate role for panel members in overseeing an agency's adherence to federal information quality guidelines.

The specification that agencies provide sufficient background information, "including background information about key studies or models" suggests that reviewers may request access to any information associated with the study. An individual panel member may justify access to a great deal of information as needed to understand "the data, analytic procedures, and assumptions" used to support the document under review.

We agree that the document alone may not be sufficient to permit an adequate review. However, the scope of information that could be requested under this language is considerable and appears to be far

more than necessary to enable an expert panel to assess the overall quality of a document. This language is more appropriate if the panel were expected to perform its own re-analysis, a function that is well-beyond the scope of the proposed review. Presumably, the panel as a whole contains a sufficient diversity of expertise to enable individual members to assist others to understand technical issues unique to a given discipline. In some cases the agency may not have access to "all underlying data" used in the model of a particular study referenced in the document. The agency should not be expected to supply an endless amount of underlying information to each panel member.

Also, the background information supplied to panel members should be supplied with the understanding that it is not to be distributed to any non-panel members or to be utilized for any purpose other than the performance of the review. Review panels should not be permitted to serve as a conduit for the distribution of information that could not be obtained by outside persons through established procedures such as the Freedom of Information Act (FOIA). The Bulletin's direction on the protection of confidential business information, intellectual property and privacy are not sufficient.

The Bulletin directs agencies to inform peer reviewers of all federal laws governing information access and quality. This review is supposed to be a scientific review, not a legal review. It is not and should not be the responsibility of these panels to determine whether agencies have complied with federal information quality guidelines. There is no reason for reviewers to be informed about federal laws governing information access and quality. It is the government's responsibility to enforce its own standards. This point was raised by EPA in their comments on the first draft of the proposal.[21]

Conclusion

Although OIRA has defined the processes mandated by this Bulletin as peer review, we continue to believe it is a wolf in sheep's clothing. This process is not designed to ensure the quality of government information. It is designed to prevent the dissemination of government information, stifle public debate, and delay legitimate government regulatory action. Nowhere in the Bulletin is there any positive direction issued to agencies or a binding requirement on OIRA to disseminate information that has undergone the mandated process. The Bulletin places no time limits on panel reviews or constraints on the number of reviews that a document could undergo before an agency may release it, especially if the agency alters the document in any way to address reviewers' comments.

The Bulletin does not establish a transparent process for the development, review and dissemination of information. While there are requirements for agencies to document and justify their choices in implementing this Bulletin and to provide opportunities for public participation and comment in peer reviews and plans for peer reviews, there are no requirements for transparency of OIRA's actions in implementing and overseeing the requirements of this Bulletin.

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[21] EPA Comments January 15, 2004. EPA's comments listed five key concerns about the original OMB Peer Review guidelines. The fourth states "Requirement to brief peer reviewers on Information Quality Guidelines (OMB's and agency's) and OMB's guidelines for regulatory analysis would provide minimal benefits compared to time and resources required."

OIRA is not required to provide written documentation in cases where the Administrator of OIRA disagrees with an agency's designation of information as influential or highly influential. There is no requirement for OIRA to provide justification to the public if it determines that a peer review was inadequate or when OIRA provides a waiver of the peer review requirements for agency information.

The Bulletin is predicated on an assumption that the public is harmed by the dissemination of "imperfect" information by the government. OIRA has demonstrated no such harm. A stronger case can be made for harm caused to the public when the government fails to disseminate information, especially when the information may have "a clear and substantial impact on important public policies or private sector decisions."

The government has an obligation to disseminate information that is truthful, not misleading, and fairly characterizes the state-of-knowledge on important issues. The agencies are in the best position to fulfill this responsibility. Information dissemination is essential to promoting full public dialogue and debate in a democratic society. The Administrator of OIRA should not be the gatekeeper for government information. OIRA should not be the ultimate judge of whether information has achieved "sufficient" quality to enter the realm of public debate.

The public's right to know and the value of information in fostering public debate on important policy issues must be weighed against any potential "harm" of releasing information that may be deficient in some way. We find more examples that demonstrate public harm from withholding information than from disseminating it.

OIRA may be recognized as "the repository of expertise concerning regulatory issues" under Executive Order 12866, but OIRA is recognized nowhere as a repository of expertise on scientific and technical information. The agencies are the repository of scientific and technical expertise. They should be given full authority to govern their own peer review procedures.

The informal and formal review periods for economically significant regulations under Executive Order 12866 were established to provide OIRA with oversight over agency rulemaking procedures. E.O. 12866 procedures ensure that OIRA will have ample opportunity in the rulemaking process to challenge an agency's justification for regulation. There is no need or justification for OIRA to micromanage agency's review procedures for scientific information. This ill-conceived, unjustified policy should not go forward.

Sincerely,

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Member of Congress

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